United States Department of Agriculture

Animal and Plant Health Inspection Service

Veterinary Services

Center for Veterinary Biologics

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CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 06-13

Subject: Transfer of Food Safety and Inspection Service (FSIS) Support of Adjuvant Reviews from FSIS to the Animal and Plant Health Inspection Service (APHIS)

To: Biologics Licensees, Permittees, and Applicants
Veterinary Services Management Team
Directors, Center for Veterinary Biologics
Area Veterinarians in Charge, VS
State Veterinarians

I. PURPOSE

The purpose of this notice is to inform interested parties that the Food Safety and Inspection Service (FSIS) has transferred official responsibility for evaluation of adjuvants used in the preparation of veterinary biologics to the Animal and Plant Health Inspection Service's Center for Veterinary Biologics.

II. BACKGROUND

The Center for Veterinary Biologics regulates veterinary biologics. Previously, the FSIS had been providing chemical, toxicological, and pathologic evaluations of new adjuvant preparations used in veterinary biologics. This arrangement was established when FSIS' function was separated from APHIS because, at that time, APHIS did not have readily available resources nor the appropriate expertise to evaluate adjuvant preparations. Currently, APHIS has the scientific resources available to perform their own adjuvant reviews, and has chosen to do these evaluations for the purpose of streamlining the adjuvant approval process for their stakeholders.

III. POLICY

Effectively immediately, all requests for evaluation of adjuvant preparations intended for use in veterinary biologics administered to food animals will be reviewed by the Center for Veterinary Biologics. VS Memorandum 800.51, Additives in Animal Biological Products, is under review and will be republished soon. Veterinary Biologics licensees, permittees, and applicants should provide data supporting requests for approval of new adjuvant preparations to their reviewer as part of the normal licensing review and approval process.

/s/ Byron E. Rippke for

Richard E. Hill, Jr.
Director
Center for Veterinary Biologics